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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,471	07/23/2003	Angel Pellicer	PELLICER1A	1686

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,471	PELLICER ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to human Rgr polypeptides comprising amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 350.

II. Claims 9-13, drawn to antibodies that bind to human Rgr polypeptides comprising the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 387.1.

III. Claim 14, drawn to methods of diagnosing T cell malignancies, comprising detecting an abnormally truncated variant of human Rgr protein in T cells, classified in class 435, subclass 7.1.

IV. Claim 15, drawn to method for treating a T cell malignancy comprising administering an antibody that binds human Rgr protein, classified in class 424, subclass 130.1.

V. Claims 16-26, 34 and 35, drawn to polynucleotides that encode a human Rgr polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 536, subclass 23.5.

VI. Claim 27, drawn to methods of diagnosing T-cell malignancy comprising detecting human Rgr polynucleotides, classified in class 435, subclass 6.

VII. Claims 28-33, drawn to antisense polynucleotides and methods treatment using antisense polynucleotides, classified in class 514, subclass 44 and class 536, subclass 24.5.

2. The inventions are distinct, each from the other, for the following reasons:

Inventions I, II and V are patentably distinct products.

The polypeptide of group I and polynucleotide of group V are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, while a polypeptide of group I can made by methods using the polynucleotides that fall within the scope of group V, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and V are patentably distinct.

Furthermore, searching the inventions of groups I and V together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and V have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides that would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers that had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group I and the antibody of group II are patentably distinct for the following reasons:

While the inventions of both group I and group II are polypeptides, in this instance the polypeptide of group I is a single chain molecule that appears to function as an oncogene, whereas the polypeptide of group II encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group II are structurally distinct molecules. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group I and group II would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody that binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group II. Furthermore, antibodies that bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group II are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group V and the antibody of group II are patentably distinct for the following reasons. The antibody of group II includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including

framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group V will not encode an antibody of group II, and the antibody of group II cannot be encoded by a polynucleotide of group V. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group V would impose a serious search burden since a search of the polynucleotide of group II is would not be used to determine the patentability of an antibody of group V, and vice-versa.

Inventions III, IV, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of diagnosing a T cell malignancy comprising detecting a polypeptide (group III), the method of treating a T cell malignancy comprising administering an antibody (group IV), and the method of diagnosing a T cell malignancy comprising detecting a polynucleotide (group VI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a

structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis of the autoimmune disease differ significantly for each of the materials. For diagnosis using the polynucleotide, hybridization may be used. For diagnosis using the antibody, quantitation of labeled antibody may be used. For treatment of T cell malignancy using antibody, the antibody is administered to a patient. Therefore, each method is divergent in materials and steps. For these reasons the Inventions III, IV and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups III, IV and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups III, IV and VI together.

The method claims of Inventions VII and any of the methods of III, IV, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The method of treating a T cell malignancy using an antisense polynucleotide (group VII), the method of diagnosing a T cell malignancy comprising detecting a polypeptide (group III), the method of treating a T cell malignancy comprising administering an antibody (group IV), and the method of diagnosing a T cell malignancy comprising detecting a polynucleotide (group VI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis of the autoimmune disease differ significantly for each of the materials. For diagnosis using the polynucleotide,

hybridization may be used. For diagnosis using the antibody, quantitation of labeled antibody may be used. For treatment of T cell malignancy using an antibody, the antibody is administered to a patient. For treatment of a T cell malignancy using antisense, an antisense polynucleotide put into contact with a patient's T cells. Therefore, each method is divergent in materials and steps. For these reasons the Inventions VII, III, IV and VI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups VII, III, IV and VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups VII, III, IV and VI together.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of group II can be used in a method of in vivo treatment of T cell malignancy.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of group II can be used in a of detecting antigen to diagnose a T cell malignancy.

Searching the inventions of Groups II together with either III or VI would impose serious search burden. The inventions of Groups II, III and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the antibodies and a method of diagnosing T cell malignancy using an antibody; or for a method of treating a T cell malignancy using an antibody are not coextensive. Group II encompasses molecules that are claimed in terms of binding to polypeptides that have a SEQ ID NO, which is a search not required for the search of Group III or VI. In contrast, the search for group III would require a text search for the method of diagnosing T cell malignancy; and the search for group VI would require a text search for methods of treating T cell malignancy.

Inventions I and any of inventions III, IV, VI and VII are unrelated because the product of group I is not used or otherwise involved in the processes of group III, IV, VI and VII.

Inventions II and any of inventions VI or VII are unrelated because the product of group II is not used or otherwise involved in the processes of groups VI and VII.

Inventions V and any of inventions III, IV or VII are unrelated because the product of group V is not used or otherwise involved in the processes of groups III, IV and VII.

In re Ochiai:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim

will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Allen Yun on February 23, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
May 25, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

SUPERVISOR, PH.D. EXAMINER